DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-235/S-011

SEP 29 1998

Parke-Davis Pharmaceutical Research
Warner-Lambert Company
Attention: Janeth L. Turner, R.N., B.S.N.
Director, Worldwide Regulatory Affairs
2800 Plymouth Road
Ann Arbor, MI 48 105

Dear Ms. Turner:

Please refer to your supplemental new drug application dated September 13, 1996 (originally submitted as a component of your supplemental new drug application, S-006), received September 16, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Neurontin (gabapentin) Capsules, 100mg, 300mg, and 400mg.

We also acknowledge receipt of your amendment dated June 17, 1998.

Please note that during the course of the review of S-006, the Division determined that S-006 was inappropriately bundled*, and consequently, split the application into two separate supplements (S-006 and S-011). Therefore, reference is also made to action letters sent to S-006, dated August 26, 1997, and April 24, 1998, that were issued prior to the unbundling of S-006.

Supplement 011 provides for revision of the **DOSAGE AND ADMINISTRATION** section of the package insert. Specifically, directions for use permit initiation of treatment with 900 mg/day by deletion of the requirement to titrate to 900 mg/day over a 3-day period.

The User Fee goal date for this application is December 18, 1998.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the attached draft labeling (package insert submitted June 17, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

*Per agency policy as expressed in the -'Interim Guidance: Separate Marketing Applications and Clinical Data for Purposes of Assesing User Fees Under the Prescription Drug User Fee Act of 1992:'

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-235/S-011." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-2850.

Sincerely yours,

9/29/98

Paul Leber, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research